Remarks/Arguments

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed July 2, 2007. Currently, claims 38-58 remain pending. Claims 38-58 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 102

On page 2 of the Office Action, claims 38-44 and 46-57 were rejected under 35 U.S.C. 102(b) as being anticipated by Gibbs et al. (U.S. Patent No. 5,330,482). After careful review, Applicant must respectfully disagree.

Turning to claim 38, which recites:

> 38. (Previously Presented) A medical device for use in a body lumen, comprising: a self-expanding body formed from struts having a compressed state and an expanded state; the body including a cold formed nickel-titanium alloy having a transformation temperature greater than a mammalian body temperature, wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body; and a sheath at least partially enclosing the body in the compressed state.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (See MPEP § 2131). Accordingly, Gibbs et al. must teach each and every element in as complete detail as is contained in claim 38.

Nowhere does Gibbs et al. appear to teach or suggest, "the body including a cold formed nickel-titanium alloy having a transformation temperature greater than a mammalian body temperature, wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body", as recited in claim 38.

In the Final Office Action, the Examiner states on page 4, "the device of Gibbs et al. is not heat treated until *after* the basket portion has already been formed". However, claim 38 recites not only "cold formed nickel-titanium allow", but also "the nickel-titanium allow exhibits linear pseudoelasticity regardless of stress applied to the body".

Pseudoelasticity can be divided into two subcategories, linear pseudoelasticity and non-linear pseudoelasticity, also called superelasticity. First, non-linear pseudoelasticity results from cold working and subsequent heat treatment, as taught by Gibbs et al. This non-linear pseudoelasticity can exhibit a relatively flat loading plateau in which a large amount of recoverable strain is possible with very little increase in stress. This flat plateau can be seen in the stress-strain curve shown in Figure 1a of the present application. Non-linear pseudoelasticity is known to occur due to a reversible phase transformation from austenite to martensite. In contrast, linear pseudoelasticity results from cold working only, with no subsequent heat treatment. Also, as shown in Figure 1b of the present application, linear pseudoelasticity does not exhibit the flat plateau of non-linear pseudoelasticity. Linear pseudoelasticity has no such phase transformation associated with it.

As can be clearly seen, Gibbs et al. teaches a nickel-titanium alloy having superelasticity, or non-linear pseudoelasticity. The Examiner appears to recognize this by distinctively pointing out that the nickel-titanium alloy of Gibbs et al. "is not heat treated until after the basket portion has already been formed". Being heat treated, the nickel-titanium alloy has non-linear pseudoelasticity. Also, throughout the specification, Gibbs et al. recites, "superelasticity", which is commonly used to refer to non-linear pseudoelasticity. Therefore, Gibbs et al. clearly does not expressly teach each and every element of claim 38, in particular, "wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body".

In the Final Office Action, the Examiner states on page 4, "whether it has been cold formed, heat treated or otherwise, nickel-titanium alloy is still nickel-titanium alloy". The Examiner also states on page 2, "the device is formed of nickel-titanium alloy, as claimed, and, accordingly, is considered to comprise the same characteristics". It appears that the Examiner is asserting that the elements of claim 38, in particular, "wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body", is inherent in Gibbs et al. However, in order to establish inherency, the missing descriptive matter must be necessarily present in the reference and that it would be so recognized by persons of ordinary skill. (See MPEP § 2131.01). Clearly, linear pseudoelasticity is not inherent in the teachings of Gibbs et al.

As discussed previously, pseudoelasticity can be divided into two subcategories, linear pseudoelasticity and non-linear pseudoelasticity. Accordingly, nickel-titanium alloy can be either linear pseudoelastic or non-linear pseudoelastic, depending on the processing. Non-linear pseudoelasticity results when the nickel-titanium alloy is heat treated. Linear pseudoelasticity results in the absence of heat treatment. Both linear and non-linear pseudoelasticity do not exist at the same time. Throughout Gibbs et al., the specification refers to superelastic nitinol, or non-linear pseudoelasticity. Also, as the Examiner indicated, the nickel-titanium alloy of Gibbs et al. is heat treated imparting superelasticity. Therefore, clearly linear pseudoelasticity is not present when non-linear pseudoelasticity is present, and as such, cannot be necessarily present or inherent. Therefore, "wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body" is not inherent in Gibbs et al.

Applicant reminds that Examiner, that for anticipation, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Thus, claim 38 is clearly not anticipated by Gibbs et al. because Gibbs et al. fails to either expressly or inherently teach each and every element of claim 38 and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, claims 39-44 and 46, which depend from claim 38 and include significant additional limitations, are believed to be not anticipated by Gibbs et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 47, which recites:

> 47. (Previously Presented) A medical device for use in a body lumen, comprising: a self-expanding body formed from struts; the body including a cold formed nickel-titanium alloy, wherein the nickel-titanium alloy is in a martensitic phase when the body is stressed into a first shape and when the body is stress relieved to a second shape, and wherein the nickel-titanium alloy has a transformation temperature >37 degrees C.; and a sheath at least partially enveloping the body in its first shape.

For similar reasons given above, as well as others, claim 47 is believed to be not anticipated by Gibbs et al. and Applicant respectfully requests withdrawal of the rejection. Additionally, for similar reasons, as well as others, claims 48-52, which depend from claim 47 and include significant additional limitations, are believed to be not anticipated by Gibbs et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 53, which recites:

> 53. (Previously Presented) A method of providing a medical device for use in a body lumen, comprising: providing struts including a cold formed nickel-titanium alloy; setting a transformation temperature >37 degrees C.; cold forming the struts into a body having a shape; stressing the body into a first shape wherein the nickel-titanium alloy is in a martensitic phase; providing a sheath; disposing the body in the first shape at least partially inside the sheath; and deploying the body from the sheath to stress relieve the body into a second shape, wherein the nickel-titanium alloy remains in the martensitic phase.

For similar reasons given above, as well as others, claim 53 is believed to be not anticipated by Gibbs et al. and Applicant respectfully requests withdrawal of the rejection. Additionally, for similar reasons, as well as others, claims 54-57, which depend from claim 53 and include significant additional limitations, are believed to be not anticipated by Gibbs et al. and Applicant respectfully requests withdrawal of the rejection.

Claim Rejections – 35 USC § 103

On page 3 of the Office Action, claims 45 and 58 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gibbs et al. (U.S. Patent No. 5,330,482). After careful review, Applicant must respectfully disagree.

For similar reasons given above, as well as others, claims 45 and 58, which depend from claims 38 and 53, respectively, and include significant additional limitations, are believed to be patentable over Gibbs et al. and Applicant respectfully requests withdrawal of the rejection.

In view of the foregoing, all pending claims, namely claims 38-58, are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully Submitted,

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By his Attorney

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